## REMARKS

This application has been carefully reviewed in light of the Office Action dated May 1, 2009. Claims 1-13, 15-22, 24-36, and 39-78 are currently pending. By this Amendment, Claims 1, 2, 4, 9, 10, 11, 16, 20, 22, 27, 34, 41, 42, 50, 55, 62, and 72 have been amended, Claims 6, 18, 46, and 57 have been canceled, and Claims 77 and 78 have been added. These amendments are made without prejudice or disclaimer, and Applicants respectfully reserve the right to pursue the original, previously presented, or canceled subject matter in continuing applications. Applicants also respectfully submit that no new matter has been added to the application by these amendments. Support for the amendments and new claims can be found, for example, in the originally filed claims, and on page 17 of the originally filed specification. Applicants respectfully submit that the claims are in condition for allowance for at least the following reasons.

### Claim Rejections under 35 U.S.C. § 112

The Office Action rejected Claims 1-76 under 35 U.S.C. § 112, first paragraph, and Claims 1-76 under 35 U.S.C. § 112, second paragraph. Applicants respectfully submit the claims are now in condition for allowance for at least the following reasons.

*35 U.S.C. § 112, First Paragraph*

The Office Action rejected Claims 1-76 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, regarding the claim limitation of "a substantially uniform porosity" in Claims 1, 34, 41, and 72, the Office Action states "there is no reference in either the original drawings or specification to the porosity being substantially uniform" (emphasis in original).

Applicants respectfully submit there is sufficient support for the claim limitation of "a membrane [having] a substantially uniform porosity" in the originally filed application. For

example, FIG. 10 illustrates a membrane 203 that one of skill in the art would recognize as having a substantially uniform porosity, i.e., close examination of the illustrated porosity reveals that each of the pores is substantially, but not exactly, equidistant from another. Furthermore, Applicants respectfully submit that it is well known in the art that the manufacturing process of a membrane may result in pores having slight variations in size, while maintaining substantially the same size for the pores.

Regarding the claim limitation of "blood flow into the aneurysm is substantially not allowed" in Claims 1, 34, 41, and 72, the Office Action states "[t]his is considered new matter since the original disclosure only states that the blood flow into the aneurysm is prevented … but it does not state that it is substantially prevented" (emphasis in original). Applicants have amended Claims 1, 34, 41, and 72 to replace the claim language "substantially not allowed" with "reduced." Applicants respectfully submit that the specification provides adequate disclosure for the claim limitation of reduced blood flow to the aneurysm by the claimed device.

The Office Action also rejected Claims 1-76 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Specifically, regarding Claims 1, 34, 41, and 72, the Office Action states "[i]t is unclear to the examiner how blood cannot pass through a portion [to an aneurysm], but can pass through another portion of the membrane [into branch vessels] if the pores are uniform."

Applicants respectfully submit the originally filed application sufficiently enables this claim feature. For example, as explained in the specification, the distance between adjacent pores of the membrane is preferably less than about 75 microns to reduce the likelihood that small branch vessels that are adjacent the implant will be blocked when the implant is deployed. Specification, p.17 ll.9-11. This is discussed in more detail below with respect to the § 112,

second paragraph, rejection, but Applicant respectfully submits that the enablement requirement is satisfied at least for the reasons above.

Accordingly, Applicants respectfully submit that the Specification provides adequate written description and enablement support for the claims under § 112, first paragraph, and respectfully request withdrawal of the rejection of Claims 1-76 under 35 U.S.C. § 112, first paragraph.

*35 U.S.C. § 112, Second Paragraph*

The Office Action rejected Claims 1-76 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the Office Action states that "[i]t is unclear … how blood cannot pass through a portion, but can pass through another portion of the membrane if the pores are uniform."

Applicants have provided the Figures A-D below to illustrate in further detail how the above-recited language is accomplished by the device claimed in the relevant claims. Applicants respectfully submit that the following description is not new matter and that the following would be appreciated by one of ordinary skill in the art at the time of filing upon review of the specification.

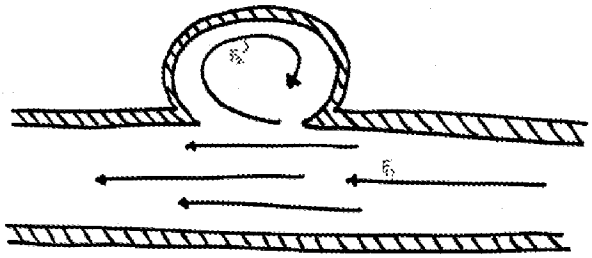

FIG. A

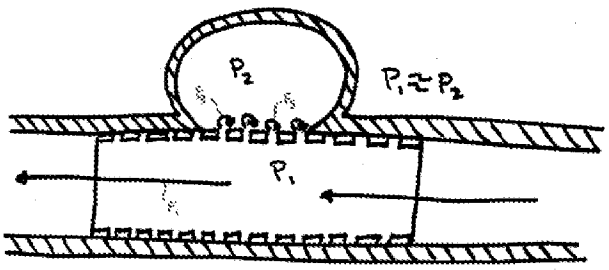


FIG. B

Figure A depicts blood flow $F_1$ through a blood vessel. As the blood flow $F_1$ passes an aneurysm arising from the blood vessel, the blood flow $F_1$ causes resultant flow $F_2$ within the aneurysm. This resultant flow $F_2$ is caused in part

by the shear forces of the blood flow $F_1$ as it passes the aneurysm and flow of blood that is redirected into the aneurysm resultant flow $F_2$.

Depicted in Figure B is the change in flow when the claimed device is inserted into the vessel adjacent the aneurysm. As depicted, the device substantially reduces the resultant flow $F_2$ by reducing the exposure of the blood inside the aneurysm to the blood flow $F_1$ through the vessel. The device reduces the shear forces between the blood within and without the aneurysm, and the resultant flow within the aneurysm is reduced to minor flow, as indicated by reduced flow $F_3$. As the aneurysm is generally closed (i.e., there is no outlet for the blood within the aneurysm), the diastolic pressure within the aneurysm $P_2$ is substantially equal to the diastolic pressure in the vessel $P_1$. Additionally, during systole, the pressure within the aneurysm $P_2$ provides a back pressure that reduces, or prevents, flow of blood through the device wall. Because of the pressure relationship within the aneurysm and within the vessel, there is little, if any, blood flow across the wall of the device. The reduced flow $F_3$ allows the blood within the aneurysm to coagulate and ultimately heal the aneurysm.

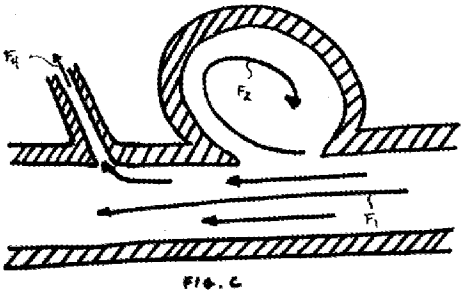

FIG. C

Figure C is similar to Figure A and illustrates blood flow $F_1$ through the vessel, resultant flow $F_2$ within the aneurysm caused by blood flow $F_1$ through the vessel, and blood flow $F_4$ through a perforator vessel adjacent the aneurysm.

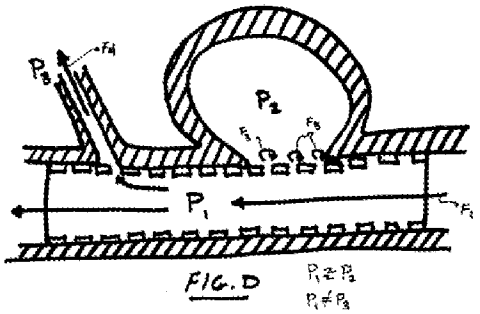

FIG. D $P_1 \neq P_2$ $P_1 \neq P_3$

Figure D illustrates the vessels and aneurysm of Figure C with the device described in the present application inserted. The changes within the aneurysm depicted in Figure D are similar to those depicted in Figure B, described above. Figure D also illustrates, however, the

continuation of blood flow $F_4$ in the perforator vessel even though the device reduces, impedes, or prevents flow $F_3$ within the aneurysm. As the perforator is open (i.e., there is an outlet for the blood in the branch vessel), the pressure $P_3$ within the perforator is less than the pressure in the vessel $P_1$, and the difference in pressure between the vessel and the perforator allows the flow of blood through the device wall into the perforator vessel so as not to inhibit blood supply functions of the perforator vessel. Moreover, the perforator vessel, being an open blood pathway, does not provide back pressure like the aneurysm, which is a closed structure, does. As described in the specification, the device is configured to provide treatment of the aneurysm (by obstructing or reducing blood flow to the aneurysm) while permitting blood flow to the perforator vessels.

Applicants respectfully submit that one of ordinary skill in the art would have understood, at the time of filing, the disclosure provided in the specification, and the relevant anatomical features and flow dynamics, sufficiently to understand that the device operates to obstruct or reduce blood flow to the aneurysm and permit flow to the perforator vessels.

Applicants respectfully submit that the amended claims highlight the structure of the membrane that facilitates the functions of treating the aneurysm and permitting blood flow to the perforator vessels. The claims recite, among other things, a substantially uniform porosity and a distance between adjacent pores of the membrane being less than about 75 microns.

For at least the reasons discussed above with regards to the rejection of Claims 1-76 under 35 U.S.C. § 112, second paragraph, Applicants respectfully submit that the originally filed specification particularly points out and distinctly claims the subject matter which the Applicants regard as the invention. Specifically, Applicants respectfully submit that the originally filed specification makes clear how blood flow into an aneurysm is reduced, obstructed, or impeded, and how blood flow into branch vessels is permitted.

The Office Action also rejected Claims 62 and 65-67 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, Claim 62 was dependent on canceled Claim 14. Applicants have amended Claim 62 to depend from Claim 41, thereby correcting a typographical error.

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 1-76 under 35 U.S.C. § 112, second paragraph.

**Claim Rejections under 35 U.S.C. § 103**

Claims 1-13, 15-20, 24-31, 35, 36, 41-56, 58, 59, 62-69, 73, and 74 are rejected under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 6,451,050 to Rudakov et al. ("Rudakov") in view of United States Patent Application No. 2002/0035394 to Fierens et al. ("Fierens"). Claims 2, 5, 18, 20-22, 42, 45, 57, and 59-61 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rudakov in view of Fierens and further in view of United States Patent No. 5,769,884 to Solovay ("Solovay"). Claims 34, 39, 40, 72, 75, and 76 are rejected under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 5,948,018 to Dereume et al. ("Dereume") in view of Fierens. Claims 32, 33, 70, and 71 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rudakov in view of Fierens and further in view of Dereume.

Each of the rejected independent Claims, namely Claims 1, 34, 41, and 72, feature a membrane that has a substantially uniform porosity over a length extending from the distal end of the membrane to the proximal end of the membrane, and a distance between adjacent pores of the membrane being less than about 75 microns, wherein the membrane obstructs blood flow from a vessel into an aneurysm such that blood flow into the aneurysm is impeded, and permits blood flow through pores in the membrane and into branch vessels, perforators, and/or microscopic branches so as not to inhibit blood supply functions of the perforators and/or

microscopic branches. Applicants respectfully submit that the cited references do not teach or suggest, alone or in combination, at least a distance between adjacent pores of the membrane being less than about 75 microns, or a membrane that obstructs blood flow from a vessel into an aneurysm such that blood flow into the aneurysm is impeded, and permits blood flow through pores in the membrane and into branch vessels, perforators, and/or microscopic branches so as not to inhibit blood supply functions of the perforators and/or microscopic branches.

Rudakov is directed to a stent graft for implantation in a vessel, but Applicants respectfully submit that Rudakov fails to teach or suggest a distance between adjacent pores of a membrane that is less than about 75 microns, in addition to a membrane that has a substantially uniform porosity over a length extending from a distal end of the membrane to a proximal end of the membrane, wherein the membrane obstructs blood flow from a vessel into an aneurysm such that blood flow into the aneurysm is impeded, and permits blood flow through pores in the membrane and into perforator vessels so as not to inhibit blood supply functions of the perforator vessels.

Fierens discloses expandable vessel stents, for reducing the risk of restenosis and thrombus formation, attached to a porous biocompatible material that may have pores of uniform density, size, and/or shape. Applicants respectfully submit that Fierenes is fails to remedy the above-mentioned shortcomings of Rudakov and is completely silent regarding distances between membrane pores; intracranial aneurysms; cranial arteries and perforator vessels; and a membrane that obstructs blood flow from a vessel into an aneurysm such that blood flow into the aneurysm is impeded, and permits blood flow through pores in the membrane and into perforator vessels, so as not to inhibit blood supply functions of the perforators.

Solovay discloses an endoprosthesis implant having a stent covering comprising a plurality of fibers, the stent covering with a first region having pores with a diameter of about 30

to about 120 meters, and the average diameter of the fibers preferably at least about three times the pore diameter of the pores in the first region. Solovay, col.2 ll.30-47. Applicants respectfully submit that Solovay fails to teach or suggest, alone or in combination with the other cited references, at least a distance between adjacent pores of a membrane that is less than about 75 microns.

Derueme is directed to expandable, supportive endoluminal grafts. Derueme does not, however, teach or even suggest that a distance between pores of the grafts is no more than about 75 μm. Accordingly, Applicants respectfully submit that Derueme fails to teach or suggest, alone or in combination with the other cited references, a device that obstructs blood flow from a vessel into an aneurysm, such that blood flow into the aneurysm is impeded, and that permits blood flow through pores in the membrane and into perforator vessels so as not to inhibit blood supply functions of the perforators vessels, as recited in the rejected independent claims.

As explained in the specification, the distance of the membrane between adjacent pores is preferably less than about 75 microns to reduce the likelihood that small branch vessels that are adjacent the implant will be blocked when the implant is deployed. Specification, p.17 ll.9-11. These small branch vessels provide blood supply to tissue, and if these small branch vessels are not provided appropriate blood supply, then the tissue that depends on the blood supply from these small branch vessels can suffer from ischemia.

While Derueme describes creation of an aperture in the implant wall, it is difficult during implantation of the Derueme device to properly align the implant with the aneurysm and account for each of the small branch vessels that are also covered by the implant. Indeed, the practitioner may not even be aware of some small branch vessels adjacent the aneurysm or the implant. The implant defined in the presently presented claims provides a device that will both obstruct blood flow to the aneurysm and, at the same time, permit blood flow through the implant to these small

branch vessels sufficient to prevent ischemia in the tissue that depends on these small branch vessels. The claimed implant permits blood flow to these small branch vessels so as not to inhibit blood supply functions of these small branch vessels. As is known in the art, blood supply function in this context include, among other things, providing adequate oxygen to brain tissue, sufficient to prevent ischemia and anaerobic conditions; providing adequate fuel, such as glucose or ketones, to brain tissue to support metabolism.

Accordingly, Applicants respectfully submit that the cited references do not teach or suggest all the features of the amended independent claims and that the amended independent claims are in condition for allowance over the cited references. Furthermore, because the remaining rejected claims depend from at least one of the rejected independent claims, Applicants respectfully submit that these dependent claims are also in condition for allowance over the cited references for the same reasons set forth above with respect to the independent claims, in addition to the patentable subject matter recited in each of these dependent claims. Therefore, Applicants respectfully request the withdrawal of the obviousness rejections of Claims 1-76 under 35 U.S.C. § 103(a).

**New Claims 77-78**

By this Amendment, Applicants have added new Claims 77 and 78. Applicants respectfully submit that Claims 77 and 78 are in condition for allowance. For example, Claim 77 recites, in part, "a porous membrane, expandable in response to expansion of the mechanically expandable device, the porous membrane: (i) having a substantially uniform porosity over a length extending from a distal end of the membrane to a proximal end of the membrane and a distance between adjacent pores of the membrane being less than about 75 microns; (ii) being secured to the mechanically expandable device, such that the proximal end of the membrane is proximate a proximal end of the mechanically expandable device, and the distal end of the

membrane is proximate a distal end of the mechanically expandable device; and (iii) being configured to, when expanded in the bodily vessel adjacent the aneurysm, reduce blood flow from the vessel into the aneurysm and permit blood supply to perforator vessels through pores of the membrane along the length of the membrane so as not to inhibit blood supply functions of perforator vessels."

Additionally, Claim 78 recites, in part, "a porous membrane, secured to the mechanically expandable device, having a substantially uniform porosity, the membrane being expandable in response to expansion of the mechanically expandable device and, when the mechanically expandable device is in the second position, the membrane comprising pores with a size between about 20 microns and about 100 microns and a distance between adjacent pores of the membrane being less than about 75 microns, such that the membrane reduces blood flow from the vessel into the aneurysm and permits blood supply to small branch vessels, branching from the vessel, through pores of the membrane so as not to inhibit blood supply functions of the small branch vessels." Applicants respectfully submit that the cited references do not teach or suggest, alone or in combination, at least these recitations. Accordingly, Applicants respectfully submit that Claim 77 and 78 be allowed in the next action.

## CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request favorable action on this application. If any questions remain, the Examiner is cordially invited to contact the undersigned attorney so that any such matters may be promptly resolved.

Any remarks in support of patentability of one claim should not necessarily be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not necessarily be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully reserve the right to traverse any of the Examiner's rejections or assertions, even if not discussed herein. Applicants respectfully reserve the right to challenge later whether any of the cited references are prior art. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. Applicants reserve the right to contest later whether a proper reason exists to combine prior art references.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502203, and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

/James W. Hill, MD/

James W. Hill, MD
Registration No. 46,396

18191 Von Karman Ave., Suite 500
Irvine, CA 92612-7108
Phone: 949.851.0633 AAS:kcc
Facsimile: 949.851.9348
**Date: September 1, 2009**

**Please recognize our Customer No. 31824 as our correspondence address.**

ORC 467224-1.077567.0021